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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,266	06/28/2000	Rama Akella	SBI-066	6018

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EXAMINER
ANDRES, JANET L

ART UNIT	PAPER NUMBER
1646	13

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/605,266	AKELLA ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *26* is/are allowed.

6)☒ Claim(s) *1-5, 8-17 and 24* is/are rejected.

7)☒ Claim(s) *6, 18-23,25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 December 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 February 2003 has been entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action. Claims 1-26 are pending and under examination in this application. Claim 22 is rejoined because allowable subject matter has been identified in a generic claim; see below.

Duplicate Claim

2. Applicant is advised that should claim 6 be found allowable, claim 25 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Objections

2. Claim 24 is objected to as being improperly dependent. Claim 11 is not drawn to a method.

Claim Rejections - 35 USC § 102

3. Claims 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. patent 5393739, Bentz et al., 1995. The '739 patent teaches a combination of a BMP and a TGF-β in column 5, line 9. BMP-3 is specifically taught in line 13 and TGF-β2 is taught in line 16.

Synthetic and recombinant proteins and thus proteins free of histones and ribosomes are taught in lines 19 and 20. Applicant's amendment limiting the intended use to the healing of skin wounds does not overcome this rejection as it was applied to claims As was stated on page 3 of the office action of paper no. 7, a new use for a known composition does not render the composition novel. A composition is a composition and its intended use does not change the nature of the composition itself.

Claim Rejections - 35 USC § 103

4. Claims 1, 3-5, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S patent 6177406 (Wang et al., 2001) in view of European application EP 0 433 225 A1 (Cerletti et al., 1991).

The '406 patent teaches in column 4, lines 29-31, that BMP-3 can be used to treat burns and incisions. Thus, the patent teaches the use of BMP-3 to treat skin wounds. Recombinant proteins, which are free of histones and ribosomal proteins, are taught in column 3, lines 27-43. Purification from bovine bone is taught in column 5, lines 60-67, column 6, and column 7, lines 1-4. The '406 patent fails to teach the use of TGF-β2 to treat skin wounds. EP 0 433 225 A1 teaches the use of "TGF-β-like" protein to treat burns and incisional wounds on p. 5, lines 13-16. TGF-β-like proteins are defined on p. 4, lines 53 and 54, to include TGF-β2 as well as TGF-β1 and TGF-β3. EP 0 433 225 A1 fails to teach the use of BMP-3 to treat skin wounds. However, it would be obvious to one of ordinary skill in the art to combine the teachings of the '406 patent with EP 0 433 225 A1 to administer BMP-3 from natural or recombinant sources, together with TGF-β2 for this purpose, as claimed in claims 1, 4, 5, 7, and 8, because the two documents teach

that they can be used for the same purpose. *In re Kerkhoven* (205 USPQ 1069, CCPA 1980) summarizes:

"It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a combination that is to be used for the very same purpose: the idea of combining them flows logically from their having been individually taught in the prior art."

For the same reason, it would be obvious to administer TGF-β1 or TGF-β3 in combination with BMP-3 with TGF-β2, anticipating the limitations of claim 3, because it too has the same purpose.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S patent 6177406 in view of EP 0 433 225 A1 as applied to claims 1, 3-5, 7, and above, and further in view of Stelincki et al. (Plastic and Resonstructive Surgery, 1998, vol. 101, pp. 12-19).

The '406 patent and EP 0 433 225 A1 teach as set forth above but fail to teach the use of an additional BMP. The use of BMP-2 to skin incisions in fetal lambs is taught by Stelincki et al.; see abstract. Stelincki et al. fails to teach the additional use of BMP-3 and TGF-β2 to treat skin wounds. However, it would be obvious to one of ordinary skill in the art to combine the teachings of Stelincki et al. with those of the '406 patent and EP 0 433 225 A1 to combine all three factors to treat wound healing. One of ordinary skill would be motivated to do so for the reasons set forth above, that all three factors are useful for the same purpose, and it is therefore *prima facie* obvious to combine them.

6. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S patent 6177406 in view of EP 0 433 225 A1 as applied to claims 1, 3-5, 7, and above, and further in view of U.S. patent 5616490 (Sullivan et al., 1997).

The '406 patent and EP 0 433 225 A1 teach as set forth above but fail to teach the use of an inhibitor of inflammation. Inhibition of TNF-α is taught by the '490 patent as a means of treating inflammatory disease; see the whole document. It would be obvious to one of ordinary skill in the art to combine the teachings of the '490 patent with the '406 patent and EP 0 433 225 A1 to arrive at the invention of claim 24; one of ordinary skill would be motivated to do so because the '490 patent teaches that inflammation is an early step in wound healing involving TNF-α and can have deleterious consequences (column 1, lines 17-56).

7. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent 6150328 and further in view of U.S. patents 5393739 and 4950483, Ksander et al., 1990. The '328 patent teaches combinations of BMP-2, BMP-3, BMP-4, BMP-5, BMP-6, BMP-7, TGF-β, and FGF for treatment of bone and cartilage defects, wound healing, and tissue repair in column 2, lines 34-65. The '328 patent does not teach the particular species FGF-1 or the species of TGF-β. FGF-1 (aFGF or acidic FGF) is taught by the '483 patent in column 2, lines 3-19. Recombinant proteins free of other proteins are taught in column 5, lines 5-8. Natural sources are taught in column 7, lines 63-67, column 8, and column 9, lines 1-7. The '483 patent does not teach the combinations set forth in the '328 patent. However, it would have been obvious to one of ordinary skill in the art to combine the teachings of the '483 patent and the '328 patent to use FGF-1 in the mixture taught by the '328 patent. One of ordinary skill would have been motivated to do so because the '483 patent teaches that this species of FGF is useful components of a wound-healing mixture. The '483 patent further teaches that FGF is useful in combination with TGF-β for wound healing (column 2, lines 9-13) but neither the '483 patent nor the '328 patent teach particular species of TGF-β. TGFs-β1, 2, and 3 are taught in the '739 patent. The '739

patent fails to teach all of the components of the claimed combination. However, it would have been obvious to one of ordinary skill in the art to combine the teachings of the '739 patent with those of the '328 patent to use the different TGF-β isoforms in the mixture taught in the '328 patent. One of ordinary skill would have been motivated to do so because the '739 teaches that these isoforms are members of the same family with the same effects on cell proliferation (column 3, lines 50-57). As stated above, Applicant's amendment limiting the intended use of the composition does not overcome this rejection. A composition is a composition, and the motivation to produce such a composition need not be the same as Applicant's; the resulting combination is the same, regardless of its intended use.

CLAIMS 1-5, 7-17, AND 24 ARE REJECTED. CLAIMS 6 AND 18-23 ARE OBJECTED TO AS DEPENDING FROM REJECTED CLAIMS BUT ARE OTHERWISE ALLOWABLE. CLAIM 25 IS OBJECTED TO AS BEING A DUPLICATE OF CLAIM 6. CLAIM 26 IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
April 30, 2003

YVONNE EYLER, PH.D
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